



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary

DATE: December 4, 2012

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Ben Brancel, Secretary
Steve Ingham, Division of Food Safety Administrator

SUBJECT: Wisconsin's Food Processing Plants and Shellfish Shippers and Processors,
Amending Ch. ATCP 70; Final Draft Rule

PRESENTED BY: Steve Ingham and Staff

REQUESTED ACTION:

At the December 18, 2012, Board meeting, the Department of Agriculture, Trade and Consumer Protection (DATCP) will ask the DATCP Board to approve a final draft rule (copy attached) amending ch. ATCP 70 related to Wisconsin's food processing plants and shellfish shippers and processors. This rule would adopt portions of the National Shellfish Sanitation Program (NSSP) Guide that would allow Wisconsin food processing plants to process, repack and ship molluscan shellfish in interstate and intrastate commerce.

SUMMARY:

Background

This proposed rule would modify ch. ATCP 70, Food Processing Plants, to incorporate changes that apply to processing molluscan shellfish (e.g., oysters, clams, mussels and certain forms of scallops). Under current rules, food processing plants in Wisconsin that perform fish processing may receive molluscan shellfish from another state and process the shellfish for final sale only within Wisconsin. The proposed rule would establish a program that allows Wisconsin food processing plants, that choose to participate in the program, to process and repack molluscan shellfish for sale in other states and internationally. Thirty-eight other states participate in the Interstate Shellfish Sanitation Conference (ISSC), which is the primary voluntary national organization of state shellfish regulatory officials. Acting under a Memorandum of Understanding with the United States Food and Drug Administration (FDA), the ISSC provides guidance and counsel on matters involving the sanitary control of shellfish. Participating states codify this guidance to regulate the processing of molluscan shellfish in their jurisdictions for interstate commerce and FDA recognizes regulations based on the guidance as suitable for ensuring compliance with the Federal Food, Drug and Cosmetic Act.

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Rule Content

This rule does all of the following:

- Defines terms related to activities associated with the receipt, processing, repacking, labeling, storage, and shipping of molluscan shellfish.
- Modifies current rules to include provisions of the National Shellfish Sanitation Program (NSSP) and the guidelines of the ISSC related to receiving, processing, repacking, labeling, storage, and shipping molluscan shellfish for wholesale interstate and intrastate trade.
- Applies existing standards for facilities, sanitation, and personal hygiene in food processing plants to molluscan shellfish shippers, reshippers and reprocessors.
- Sets standards for critical control points, critical limits, record-keeping and traceability, consistent with NSSP guidelines.

Analysis and Supporting Documents Used to Determine Effect on Small Business or in Preparation of the Economic Impact Analysis

This rule will not have a significant fiscal impact on state government and DATCP will absorb any costs with current budget and staff since food processing plants are already regulated by DATCP. This rule will have no fiscal effect on local governments or public utility rate payers. To determine the potential economic impact of the rule, the department posted the rule on the department website and the state of Wisconsin administrative rules website, and contacted appropriate organizations to solicit information and advice from businesses, business sectors, associations, local governmental units, and individuals that may be affected by the proposed rule.

Effect on Small Business

This rule will have a positive impact on businesses in Wisconsin. Currently, Wisconsin businesses may receive and process molluscan shellfish from out of state, but may only sell these products within Wisconsin. This rule will allow Wisconsin businesses to expand their markets for shellfish by allowing them to process and sell molluscan shellfish in interstate commerce. In addition, this rule may provide an incentive to large wholesalers that operate in Iowa, Minnesota, and the Dakotas to locate molluscan shellfish processing operations in Wisconsin.

The implementation costs for businesses to participate in this program are expected to be minimal. The provisions of this rule are consistent with general facility and sanitation standards that food processors must already meet. Businesses that choose to participate in the program would not need to extensively modify existing facilities or implement unusually burdensome recordkeeping. Participation in the program is voluntary and only businesses that choose to sell molluscan shellfish in interstate commerce would be required to meet the requirements. There will be no additional licensing fees beyond those already required for a food processing plant license.

This rule will primarily benefit large businesses that provide wholesale food products to retail food establishment, restaurants, and other wholesale food industries nationwide. Small businesses are unlikely to participate in this program, with current regulations allowing them to receive and sell molluscan shellfish in their local market areas. Any business, regardless of size, that sells molluscan shellfish products in interstate commerce must meet NSSP requirements. A small business that chooses to participate in the program is expected to be able to easily meet program requirements. In addition, DATCP would also provide support and guidance to any small business interested in participation to ensure they meet Hazard Analysis Critical Control Points (HACCP) and other regulatory requirements.

Public Hearings

DATCP held three public hearings on the following dates and locations:

October 9, 2012	Madison
October 11, 2012	Waupaca
October 12, 2012	Green Bay

Following the public hearings, the hearing record remained open until October 25, 2012 for additional written comments. No one attended the public hearings. The department received written and oral comments from FDA, represented by two Regional Shellfish Specialists (See Appendix A). FDA recommended the addition of provisions related to equipment, sanitation, and processing requirements beyond what is already required in ATCP 70. FDA also recommended including details associated with inspection frequencies, the certification process for shellstock shippers, shucker-packers, repackers, reshippers and depuration processors; detailed HACCP plan requirements for shellfish processors; lot identification to be used when shellstock undergoes intermediate processing or is sold from dealer to dealer; lot identification of in-shell products; and shellfish processors' and DATCP's responsibilities when an illness outbreak is linked to shellfish.

Changes from the Hearing Draft

The rule was revised to make technical changes in response to comments received from the FDA. DATCP also made changes suggested by the Legislative Council Rules Clearinghouse.

Next Steps

If the Board approves this final draft rule, the department will transmit the final draft rule to the Governor for his written approval. After DATCP receives written approval from the Governor, DATCP will submit the rule to the Legislature for review by appropriate legislative committees. If the Legislature takes no action to halt the rule, the Secretary will sign the final rulemaking order and transmit it for publication.

Appendix A – Comment Summary

Ch. ATCP 70, Food Processing Plants

Rules Clearinghouse No. 12-037

DATCP Docket No. 11-R-5

Person/Organization	Comments
FDA- Regional Shellfish Specialists John Jaworski and Gary Wolf	FDA recommended the addition of provisions related to equipment, sanitation, and processing requirements beyond what is already required in ATCP 70. FDA also recommended including details associated with inspection frequencies, the certification process for shellstock shippers, shucker-packers, repackers, reshippers and depuration processors; detailed HACCP plan requirements for shellfish processors; lot identification to be used when shellstock undergoes intermediate processing or is sold from dealer to dealer; lot identification of in-shell products; and shellfish processors' and DATCP's responsibilities when an illness outbreak is linked to shellfish.

**PROPOSED ORDER
OF THE WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION
AMENDING, CREATING AND ADOPTING RULES**

- 1 The Wisconsin department of agriculture, trade and consumer protection proposes the following
2 rule *to amend* subch. IV of ch. ATP 70 (title); and *to create ss. ATP 70.05 (1m) (am), 70.07*
3 *(8) and 70.21; relating to* regulation of Wisconsin's food processing plants and shellfish shippers
4 and processors and affecting small business.

**Analysis Prepared by the Department
of Agriculture, Trade and Consumer Protection**

This rule would modify ch. ATP 70, Food Processing Plants, to adopt portions of the National Shellfish Sanitation Program (NSSP) Guide and to allow Wisconsin food processing plants to process and ship shellfish in interstate commerce.

Statute Interpreted

Statute Interpreted: s. 97.29 (2), Stats.

Statutory Authority

Statutory Authority: ss. 93.07 (1), 97.09 (4) and 97.29 (5), Stats.

Explanation of Agency Authority

DATCP has broad general authority, under s. 93.07 (1), Stats., to interpret laws under its jurisdiction. DATCP also has general authority, under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under s. 97.29 (5), Stats., to promulgate rules related to food processing, including food handling and storage, sanitary production and processing, and food sources and labeling.

Related Statutes or Rules

Related statutes include Ch. 97, Stats., "Food Regulation", and food safety rules in chs. ATP 55 to 88, Wis. Adm. Code.

Plain Language Analysis

Background

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- Applies existing standards for facilities, sanitation, and personal hygiene in food processing plants to molluscan shellfish shippers, reshippers and reproducers.
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Environmental Impact

This rule will not have any environmental impact.

Summary of, and Comparison with, Existing or Proposed Federal Statutes and Regulations

There are no federal laws related to the transportation and processing of molluscan shellfish. However, FDA administers NSSP, which developed a model ordinance that states may use to develop uniform shellfish regulations. Compliance with the model ordinance is deemed consistent with meeting applicable provisions in the Federal Food, Drug and Cosmetic Act.

Comparison with Rules in Adjacent States

Illinois and Michigan currently participate in NSSP. Illinois' rules and Michigan's statutes and rules are consistent with this proposed rule. Unlike this proposed rule, Illinois and Michigan require molluscan shellfish processors to pay additional fees to participate in the program. Iowa

and Minnesota do not participate. These states may be potential customers for molluscan shellfish sold by Wisconsin businesses.

Summary of Factual Data and Analytical Methodologies

DATCP staff reviewed information to determine the extent to which other states have adopted NSSP guidelines and contacted staff in Illinois involved with regulating molluscan shellfish to determine the extent to which their rules are consistent with this proposed rule. DATCP obtained additional information about the applicable requirements through communications and training with FDA officials overseeing NSSP.

Standards Incorporated by Reference

This rule incorporates by reference Section IV Chapter III .01 of the Shellfish Industry Equipment Construction Guide, National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2009. Consent will be requested from the Attorney General to incorporate these standards by reference. A copy of this document will be kept on file with the department and the Legislative Reference Bureau. The Shellfish Industry Equipment Construction Guide is also available in electronic format at: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm070560.htm>

Agency Contact Person:

Questions and comments related to this rule may be directed to:

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Telephone (608) 224-4716
E-Mail: Timothy.Anderson@wisconsin.gov

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- 1 **SECTION 1.** ATCP 70.05 (1m) (am) is created to read:
- 2 ATCP 70.05 (1m) (am) If used, finger cots or gloves shall be:
- 3 1. Made of impermeable materials, except where the use of such material is
- 4 inappropriate or incompatible with the work being done.
- 5 2. Sanitized at least twice daily or more often if necessary.

1 3. Properly stored until used.

2 4. Maintained in a clean, intact, and sanitary condition prior to use.

3 **SECTION 2.** ATCP 70.07 (8) is created to read:

4 ATCP 70.07 (8) ICE. Ice used to cool or maintain the temperature of foods shall be made
5 from potable water. Ice used to cool or maintain the temperature of ready-to-eat foods shall not
6 have been previously used for any other purpose. Ice shall be received, handled, and stored in a
7 manner to prevent contamination or adulteration. Any ice which is not made on site shall be
8 inspected upon receipt, and rejected if it is delivered in a way that has not adequately protected
9 the ice from contamination.

10 **SECTION 3.** Subchapter IV of ch. ATCP 70 (title) is amended to read:

11 **Subchapter IV – Fish Processing Plants; Molluscan Shellfish Plants; Supplementary**
12 **Requirements.**

13 **SECTION 4.** ATCP 70.21 is created to read:

14 **ATCP 70.21 Molluscan shellfish processing. (1) DEFINITIONS.** In this section:

15 (a) “Blower” means a device used for washing shucked shellfish which uses forced air as
16 a means of agitation.

17 (b) “Broker” means any person who is not a dealer but who arranges the packaging,
18 shipping, sale, or distribution of molluscan shellfish without taking ownership or physical
19 custody of the shellfish.

20 (c) “Certification” or “certify” means the issuance of a numbered certificate to a licensee
21 dealer for a particular activity or group of activities that indicates approval from the department
22 to conduct the activity and compliance with this chapter.

(d) "Certification number" means the number that conforms to the United States food and drug administration generated-number in the ICSSL.

(e) "Commingle" means the act of combining different lots of food, including shellstock or shucked shellfish.

(f) "Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of an identified food safety hazard.

(g) "Cull" means to remove dead or unsafe shellstock from a lot of shellstock.

(h) "Dealer" means a licensee to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, or reshipper.

(i) "Depuration processor" means a person who harvests or receives shellstock from growing areas designated in an approved or conditionally approved, restricted, or conditionally restricted classification by the governing authority and submits such shellstock to an approved depuration process.

(j) "Dry storage" means the storage of shellstock out of water.

(k) "Growing area" means any site which supports or could support the propagation of shellstock by natural or artificial means.

(L) "Harvest area" means a growing area from which commercial quantities of shellstock may be removed and may include aquaculture sites and facilities.

(m) "Harvester" means a person who takes shellstock by any means from a growing area.

1 (n) "Heat shock" means the process of subjecting shellstock to any form of heat
2 treatment to facilitate shucking, including steam, hot water or dry heat, without substantially
3 altering the physical or organoleptic characteristics of the shellfish.

4 (o) "ICSSL" means the Interstate Certified Shellfish Shippers List, United States food
5 and drug administration publication of shellfish dealers, domestic and foreign, who have been
6 certified by a state or foreign authority.

7 (p) "In-shell product" means non-living, processed shellfish with one or both shells
8 present.

9 (q) "In-shell product packing" means the process of placing in-shell product into
10 containers for introduction into commerce.

11 (r) "Label" means any written, printed or graphic matter affixed to, or appearing upon,
12 any package containing shellfish.

13 (s) "Licensee dealer" means a plant licensed in Wisconsin for the activities of shellstock
14 shipper, shucker-packer, repacker, or reshipper.

15 (t) "Lot of in-shell product" means a single type of container of in-shell product from no
16 more than one day's harvest from a single defined growing area.

17 (u) "Lot of shellstock" means a single type of bulk shellstock or containers of shellstock
18 from no more than one day's harvest from a single defined growing area.

19 (v) "Lot of shucked shellfish" means a collection of containers of no more than one
20 day's shucked shellfish, produced under conditions as nearly uniform as possible and designated
21 by a common container code or marking.

(w) "Molluscan shellfish" means any edible species, whether shucked or in one or 2 shells, of fresh or frozen oysters, clams, mussels, or edible portions of such species, or scallops 3 except when the product consists entirely of the shucked adductor muscle.

(x) "NSSP" means the National Shellfish Sanitation Program.

(y) "Person" means any individual, receiver, trustee, guardian, fiduciary, or 6 representative of any kind, and any partnership, association, corporation or other entity.

"Person" includes the federal government, the state and any other public or private entity.

(z) "Potable water" means water obtained from a source that meets the requirements of 9 ch. NR 809.

(aa) "Raw shellfish" means shellfish that have not been thermally processed to an internal 11 temperature of at least 145°F (62.8°C) for at least 15 seconds (or a temperature-time combination 12 of equivalent lethality), or to an extent that the organoleptic characteristics of the shellfish are 13 altered.

(bb) "Repacker" means any licensee dealer, other than the original certified shucker- 15 packer, that repackages shucked shellfish into other containers.

(cc) "Repack shellstock" means the practice of removing shellstock from containers and 17 placing it into other containers.

(cc) "Reshipper" means a licensee dealer that purchases shucked shellfish or shellstock 19 from shellstock shippers, shucker-packers, and repackers and sells the product, without 20 repacking or relabeling, to other dealers, wholesalers, or retailers.

(dd) "Restricted use shellstock" means shellstock that is harvested from growing areas 22 classified by the governing authority as approved under conditions that do not allow the sale of

1 shellstock for direct marketing for raw consumption and is identified with a tag indicating that
2 the shellstock is intended for further processing prior to distribution retail or food service.

3 (ee) "Shellstock" means live molluscan shellfish in the shell.

4 (ff) "Shellstock packing" means the process of placing shellstock into containers for
5 introduction into commerce.

6 (gg) "Shellstock shipper" means a licensee dealer that grows, harvests, buys, repacks and
7 sells shellstock, or transports shucked shellfish but may not shuck shellfish or repack shucked
8 shellfish.

9 (hh) "Shucker-packer" means a licensee dealer that shucks and packs shellfish and may
10 act as a shellstock shipper or reshipper or may repack shellfish originating from other certified
11 dealers.

12 (ii) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.

13 (jj) "Transaction record" means the form or forms, used to document each purchase or
14 sale of shellfish at the wholesale level, and including shellfish harvest and sales records, ledgers,
15 purchase records, invoices and bills of lading.

16 (kk) "Wet storage" means the storage by a licensee dealer of shellstock from growing
17 areas designated in the approved classification or in the open status of the conditionally approved
18 classification by the governing authority, in containers or floats in natural bodies of water or in
19 tanks containing natural or synthetic seawater at any permitted land-based activity or facility.

20 (2) PROHIBITED ACTS. (a) In order to ensure that molluscan shellfish in commerce in
21 this state is not adulterated or misbranded as defined in ss. 97.02 and 97.03, Stats., it is unlawful
22 to process, store, transport, handle, or sell molluscan shellfish or molluscan shellfish products

1 unless the molluscan shellfish is received and tagged as coming from a certified dealer and
2 thereafter protected from contamination and unclean, unhealthy, or insanitary conditions.

3 (b) No licensee may operate as a licensee dealer without providing the department with a
4 business address at which inspections of facilities, activities, or equipment can be conducted, and
5 obtaining certification from the department.

6 (c) Only a licensee dealer may handle, receive, store, sort, shuck, repack or otherwise
7 process molluscan shellfish for interstate commerce.

8 (d) No person may shuck shellfish for interstate commerce without being certified as a
9 shucker-packer.

10 (e) No person may repack shucked shellfish for interstate commerce without being
11 certified as a shucker-packer or repacker.

12 (f) No person may repack shellstock for interstate commerce without being certified as a
13 shellstock shipper, shucker-packer, or repacker.

14 (g) No person may ship shellstock in interstate commerce without being certified as a
15 shellstock shipper, shucker-packer, or repacker.

16 (h) No person may purchase shellstock or shucked shellfish from licensee or certified
17 dealers and sell the product in interstate commerce, without repacking or relabeling, to other
18 licensee or certified dealers, wholesalers or retailers without being certified as a reshipper.

19 (i) No licensee dealer may commingle, sort, or repack shellstock or shucked shellfish in
20 a way that loses the identity of the lot.

21 (j) No licensee dealer may handle, store, process or ship shellstock or shucked shellfish
22 unless it is accompanied by an existing tag or label, or a tag or label that accurately reproduces
23 all information on the original tag or label that accompanied the lot or shipment.

1 (k) No licensee dealer certified as a reshipper may conduct wet storage activities.

2 (3) LICENSEE DEALER CERTIFICATION AND ENFORCEMENT. (a) A licensee dealer

3 requesting certification shall be subject to a comprehensive, on-site inspection by a standardized
4 department representative not more than 120 days before issuance or renewal of certification,
5 and shall comply with par. (b) or (c). The department shall ensure that each certification meets
6 all of the following:

7 1. Certification shall expire annually, with the expiration month set by the department.

8 2. Only one certification number shall be issued for each licensee dealer.

9 3. Each certification number shall be unique.

10 (b) Initial certification shall be given only to a licensee dealer once all of the following
11 requirements have been met:

12 1. The department has approved any HACCP plans developed by the licensee dealer to
13 meet the requirements of sub. (18).

14 2. The department has determined that the licensee dealer is in substantial compliance
15 with subch. II and subs. (5) to (16) and (18).

16 3. The department has approved construction, operational, and remodeling plans, if
17 appropriate, for wet storage operations.

18 (c) Renewal of certification shall be given only to a licensee dealer upon determination
19 by the department that the licensee dealer is in substantial compliance with subch. II and subs.
20 (5) to (16) and (18).

21 (d) No licensee dealer may operate as a licensee dealer with a revoked or suspended
22 certification.

1 (e) Upon certification of a licensee dealer, the department shall notify the United States
2 food and drug administration for the purpose of having the licensee dealer listed in the ICSSL.

3 (f) Upon suspension or revocation of a licensee dealer's certification, the department
4 shall notify the United States food and drug administration for the purpose of having the licensee
5 dealer removed from the ICSSL.

6 (g) The department shall inspect licensee dealers as required by one of the following:

7 1. Within 30 days of the licensee dealer beginning activities if the initial certification was
8 based on a pre-operational inspection.

9 2. At least monthly for a licensee dealer certified as a depuration processor.

10 3. At least quarterly for a licensee dealer certified as a shucker-packer or repacker.

11 4. At least semiannually for a licensee dealer certified for other activities or operation of a
12 wet storage operation.

13 5. At least annually for a licensee dealer who has demonstrated a history of satisfactory
14 compliance for the past 3 years.

15 (h) The department shall provide the licensee dealer with a report describing the findings
16 of each inspection, including a listing of deficiencies and corresponding citations of this chapter.

17 (i) When an inspection detects a deficiency that is critical for the protection of public
18 health, the licensee dealer shall correct the deficiency during that inspection, or cease production
19 affected by the deficiency, or the department shall begin the revocation or suspension of the
20 licensee dealer's certificate.

21 (j) The department shall notify a licensee dealer, who is certified for wet storage, within
22 24 hours of any change in growing area classification or status affecting the operation of the wet
23 storage facility.

1 (4) COMPLIANCE. A licensee dealer shall comply with subch. II and 21 CFR Part 123.

2 (5) TRUCKS ONLY LICENSEE. A licensee dealer, whose facilities consist of trucks only,
3 shall have either a licensed facility for the storage of shellfish, or arrangements with an
4 appropriately licensed facility for the storage of shellfish and a permanent business address at
5 which records are maintained and inspections of those records can be performed.

6 (6) EQUIPMENT AND FACILITIES. (a) Before licensing, the department shall review all
7 equipment for conformance with the Shellfish Industry Equipment Construction Guide, Section
8 IV Chapter III .01, of the NSSP (2009). All equipment shall be constructed in a manner, and
9 with materials, that can be cleaned and sanitized, maintained, or replaced in a way that prevents
10 contamination of shellfish products.

11 **Note:** A copy of the Shellfish Industry Equipment Construction Guide is on file with the
12 department and the legislative reference bureau. You may also obtain a copy from
13 the following website: [http://www.fda.gov/Food/FoodSafety/Product-](http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm070560.htm)
14 [SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationPro](http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm070560.htm)
15 [gram/ucm070560.htm](http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/NationalShellfishSanitationProgram/ucm070560.htm).
16

17 (b) A licensee dealer who is a certified shucker-packer shall provide shucking blocks
18 which are solid, of one-piece construction, and easily removed from the shucking bench unless
19 the block is an integral part of the bench. Shucking benches, contiguous walls, and stands or
20 stalls and stools for shuckers shall be made of easily cleanable, corrosion-resistant impervious
21 materials which are free from cracks. Shucking benches shall drain completely and rapidly away
22 from any shellfish on the benches.

23 (c) When monitoring product temperatures, the licensee dealer shall use a temperature
24 measuring device accurate to within 2°F (1°C).

25 (d) All equipment used in heat shock processing shall comply with the requirements of
26 subch. II and this subchapter.

(e) All equipment used to handle ice shall be of sanitary design and construction, and kept clean and stored in a sanitary manner.

(f) Shellstock washing storage tanks and related plumbing shall be of sanitary design and construction, easily accessible for cleaning and inspection, self-draining, and cleaned and sanitized in the same manner as other food contact surfaces.

(g) Facilities for shucking and packing activities shall be separated by use of separate rooms, partitions, or sufficient spacing. Other food manufacturing activities which could result in the contamination of shellfish shall be separated by adequate barriers.

(h) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are prohibited.

(i) All door and window screens shall be not less than 15 mesh per inch.

(7) SANITATION. A licensee dealer shall comply with the sanitation requirements of subch. II and ensure that all of the following apply:

(a) Any operations water from a private source shall be sampled by a person recognized by the department and tested at a laboratory licensed by the department before use of the water supply, every 6 months while the water supply is in use, and after the water supply has been repaired and disinfected.

(b) Shellstock washing shall only be done using water from a potable water supply. If recirculated water is used to wash shellstock, the licensee dealer shall obtain approval for the construction or remodeling of the system and its operation from the department, treat the water so that it is potable and does not leave any unacceptable residues on the shellstock, and test the microbiological quality of the water daily.

(c) Employees working in both shucking and packing activities shall wash their hands before beginning shucking or packing. Employees shall comply with handwashing requirements

of this chapter and after each handwashing shall sanitize their hands in a handwashing facility that meets all of the following requirements:

1. Supplies warm water at a temperature of at least 100°F (37.8°C), and shall be directly plumbed to an approved sewage disposal system.

2. Contains at least one handwashing sink available in a room used for shellfish packing.

3. Has a posted sign clearly visible to all employees at each handwashing sink that indicates handwashing is required. Each sign shall be translated in one or more languages understood by the employees using the sink.

(d) No clothing or personal belongings shall be stored in any area where shellfish are shucked or packed, and in any area which is used for the cleaning or storage of utensils used to shuck or pack shellfish.

(e) All employees shall immediately report to the licensee dealer any symptoms of disease transmissible through food. This reporting shall be in a manner that allows the licensee dealer to reduce the risk of shellfish-borne disease transmission, including providing information such as previous exposure to shellfish-borne disease, date of symptom onset, description of symptoms, and a diagnosis by a health practitioner. The licensee dealer shall notify the department within one working day when informed by an employee of hepatitis symptoms or diagnosis, and shall take immediate action to ensure that the employee is excluded from working in any capacity in which they may contact shellfish, contact food contact surfaces, or transmit the illness to other employees.

(f) The licensee dealer shall ensure that the only toxic substances present in the facility are those necessary for plant activities. Separate storage shall be provided for pesticides;

detergents, sanitizers, and other related cleaning agents; and strong acids, bases, polishes, and other chemicals. No toxic substances shall be stored above shellfish or food contact surfaces.

(g) Chemicals, including those used for cleaning or sanitizing, and toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

(h) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table.

(8) SUPERVISION AND TRAINING. (a) A licensee dealer shall designate an employee to supervise general plant management and activities.

(b) The supervisor shall be trained in proper food handling techniques and principles of food protection, and be knowledgeable of personal hygiene and sanitary practices.

(c) A licensee dealer shall ensure that the supervisor monitors sanitation and employee hygiene practices for compliance with the requirements of this chapter.

(d) A licensee dealer shall ensure that employees are trained in proper food handling, sanitation, and personal hygiene practices necessary for compliance with the requirements of this chapter.

(9) RECEIVING. (a) *Shipment acceptability*. Fresh molluscan shellfish shipments shall be considered acceptable when all of the following apply:

1. Each shipment is properly identified with tags and shipping documents.

2. All shellstock in the shipment is alive and cooled to an internal shellstock body temperature of 50°F (10°C) or less.

3. All shucked shellfish in the shipment is cooled to a temperature of 45°F (7.2°C) or less.

1 4. If the time-temperature indicating device shows that the ambient air temperature has
2 exceeded 45°F (7.2°C) but the shellstock internal body temperature is 50°F (10°C) or less.

3 5. All other conditions of shipment in this chapter are met.

4 (b) *Shipment rejection*. The department shall notify the shipper, the licensee dealer, and
5 the state where the shipment originated, of a shipment's rejection, when the department
6 determines any of the following have occurred: 1. Any molluscan shellfish are not properly
7 identified with tags or shipping documents.

8 2. Any internal shellstock body temperature exceeds 60°F (15.6°C).

9 3. Any shucked shellfish temperature exceeds 50°F (10°C).

10 4. Any shellfish purchased as frozen has thawed.

11 5. Any other reason that the product is adulterated or unsafe for human consumption.

12 (c) *Receiving molluscan shellfish*. The licensee dealer receiving molluscan shellfish
13 shall do all of the following:

14 1. Reject or discard any molluscan shellfish shipments which do not originate from a
15 licensed harvester or dealer listed in the ICSSL, are unwholesome or adulterated, inadequately
16 protected, or whose source cannot be identified.

17 2. Place molluscan shellfish under temperature control within 2 hours after receipt from
18 the harvester or when the shipper is also the harvester, when shellstock reaches the shipper's
19 facility.

20 3. Ensure that once shellstock is placed in storage under temperature control and until
21 sale to the processor or final consumer, it shall meet all of the following conditions:

22 a. The shellstock shall be iced or placed and stored in a storage area or conveyance with
23 ambient air temperature maintained at 45°F (7.2°C) or colder.

1 b. The shellstock shall not be permitted to remain without ice, mechanical refrigeration
2 or other approved methods of refrigeration for more than 2 hours at points-of-transfer such as
3 loading docks.

4 c. The shellstock shall not be permitted to be placed in wet storage.

5 4. Ensure that frozen shellfish remains frozen.

6 **(10) SHELLSTOCK IDENTIFICATION.** (a) The licensee dealer shall buy shellstock only
7 from sources listed in the ICSSL.

8 (b) The licensee dealer shall keep the harvester's tag affixed to each container of
9 shellstock until the container is either shipped, or emptied to wash, grade or pack the shellstock.

10 (c) The identification tags of the licensee dealers shall be durable, waterproof, and
11 approved by the department prior to use, at least 13.8 square inches in area, and contain all of the
12 following indelible, legible information in the order specified below:

13 1. The licensee's name, address and certification number as assigned by the department.

14 2. The original shellstock shipper's license or certification number. If the shellstock has
15 been depurated, the original shellstock shipper's certification number is not required.

16 3. The date of harvest, or date of depuration processing, the original harvest date and
17 any harvest date from wet storage.

18 4. The wet storage or depuration cycle or lot number, if the shellstock has been wet
19 stored or depurated. The wet storage lot number shall begin with the letter "w."

20 5. The most precise identification of the harvest location as is practicable including the
21 capital initials of the state of harvest, and the designation of the growing area by indexing,
22 administrative or geographic designation.

1 6. When the shellstock has been transported across state lines and placed in wet storage
2 in a licensee dealer's operation, the statement "This product is a product of (name of state) and
3 was wet stored at (facility certification number) from (date) to (date) ."

4 7. The type and quantity of shellstock.

5 8. In bold capitalized type on each tag, the statement **"THIS TAG IS REQUIRED TO**
6 **BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND**
7 **THEREAFTER KEPT ON FILE FOR NINETY DAYS."**

8 9. All shellstock intended for raw consumption shall include a consumer advisory with
9 the statement "Retailers, inform your customers of the following: Consuming raw or
10 undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne
11 illness, especially if you have certain medical conditions" or an equivalent statement

12 10. The statement "Keep Refrigerated" or an equivalent statement.

13 (d) When both the licensee dealer and harvester tags appear on the container, the licensee
14 dealer's tag is not required to duplicate the information on the harvester's tag.

15 (e) If the shellstock is removed from the original container, the tag on the new container
16 shall meet the requirements in par. (c). If the shellstock is received bearing a restricted use tag,
17 all restricted use language shall be transferred to the new shipping tag.

18 (f) When shellstock intended for retail sale is packed in containers of not more than 5
19 pounds, and shipped in a master container which includes a tag in compliance with this chapter,
20 the individual containers are not required to be tagged, but may be labeled in some other manner
21 with indelible, legible information which is adequate for tracing the shellfish back to the lot of
22 shellstock from which it originated.

(11) TAGGING OF SHELLSTOCK LOTS DURING INTERMEDIATE PROCESSING. (a) When the shellstock is removed from the original container, the licensee dealer shall do all of the following:

1. Keep the harvester tag for 90 days.
2. Keep a record of the growing area and date of harvest for shellstock.
3. Maintain the lot identity of all shellstock during any intermediate stage of processing.

(b) A licensee dealer receiving bulk tagged lots of shellstock shall have an intermediate processing plan approved by the department to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification.

(c) In order for a licensee dealer to tag a lot container of shellstock, instead of meeting the requirement in sub. (10) (c), for a harvester or licensee tag on each individual container, the licensee dealer shall have an intermediate processing plan approved by the department which establishes the procedures the licensee dealer shall use to tag the lot during the washing, packing or staging of molluscan shellfish.

(d) Unless the licensee dealer is included in a commingling plan approved by the department, the licensee dealer's intermediate processing plan for tagging a lot of shellstock during the intermediate stage of processing shall ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification. The identification shall be provided by a harvester's or licensee dealer's tag which meets the requirements of this chapter, or a tag for each lot of shellstock that contains all of the following:

1. The statement "All shellstock containers in this lot have the same harvest date and area."
2. The harvest date and growing area.

1 3. The original dealer certification number.

2 4. The number of individual containers in each lot of shellstock unit after washing,
3 packing or staging has been completed.

4 (e) When a licensee dealer has an intermediate processing plan approved by the
5 department, the licensee dealer shall tag each lot of shellstock in accordance with the
6 intermediate processing plan while the lot of shellstock is being processed in the licensee
7 dealer's facility.

8 (f) All restricted use shellstock shall include a tag containing all information required in
9 this chapter and specific language indicating the intended use of the shellstock.

10 (g) If shellstock is sold in bulk, the licensee dealer shall provide a transaction record
11 prior to shipment. This transaction record shall contain the name of the consignee and all
12 information specified in sub. (10) (c).

13 **(12) BULK TAGGING SHELLSTOCK LOTS FOR SALES BETWEEN LICENSEE DEALERS.** (a)
14 When a single lot of shellstock is sold, multiple containers may be placed on a wrapped pallet, in
15 a tote, in a net bailer, or another container, and the unit tagged with a single tag in accordance
16 with sub. (10) (c).

17 (b) This bulk tagging provision shall not apply to sales to re-shippers.

18 (c) The shipment shall be accompanied by a transaction record stating the name of the
19 consignee who shall be a certified dealer.

20 (d) The unit tag shall include the statement "All shellstock containers in this lot have the
21 same harvest date and area of harvest," the number of individual containers in the unit, and the
22 requirements specified in sub. (10) (c).

1 (13) PROCESSING. (a) *Shellstock processing*. When processing shellstock, a licensee
2 dealer shall do all of the following:

3 1. For shellstock refrigerated prior to shucking, chill the shucked meats to an internal
4 temperature of 45° F (7.2°C) or less, within 4 hours of removal from refrigeration.

5 2. Ensure that shellstock for shucking is reasonably free of sediment and is not placed in
6 containers with standing water for the purposes of washing shellstock or loosening sediment.

7 3. Cull to remove any dead or damaged shellstock.

8 4. Wash, blow, and rinse all shellfish meats in accordance with 21 CFR Part 161.130.

9 5. Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after
10 delivery to the packing room.

11 6. Not commingle shellstock lots during shucking unless all shellfish is from licensee
12 dealers included in a commingling plan approved by the department.

13 7. Not allow the use of dip buckets for hand or knife rinsing, or sanitizing.

14 8. A licensee dealer that uses heat shock to prepare shellstock for shucking shall do all of
15 the following:

16 a. Use only a scheduled heat shock process approved by the department. The scheduled
17 process may be developed by the department or qualified persons with adequate facilities
18 conducting the appropriate studies of critical factors including the type and size of shellfish, time
19 and temperature of exposure, type of process, size of tank, tunnel or retort; water-to-shellfish
20 ratios in tanks, and temperature and pressure monitoring devices.

21 b. Post the schedule for the heat shock process in a conspicuous location.

22 c. Make sure all responsible persons are familiar with the requirements.

d. Cool all hot shellstock immediately after the heat shock process by either dipping in an ice bath or using flowing potable water.

e. If a heat shock water tank is used, and the water is maintained at or above a temperature of 140°F (60°C), completely drain and flush the tank at the end of each day's operation so that all mud and debris in the dip tank are removed. If the temperatures are maintained below 140°F (60°C),, completely drain and flush the tank at not less than 3 hour intervals.

(b) *Shucked shellfish processing.* When processing shucked shellfish, a licensee dealer shall do all of the following:

1. If heat shock is used, once heat shocked shellstock is shucked, cool the shucked shellfish meats to 45°F (7.2°C) or less, within 2 hours after the heat shock process.

2. Wash, blow, and rinse all specified shucked shellfish meats in accordance with 21 CFR Part 161.130.

3. Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room.

4. Completely empty shucking buckets at the packing room so no overage is returned to the shucker.

5. Store shucked and packed shellfish in covered containers in the storage area at an ambient air temperature of 45° F (7.2°C) or less.

6. Store packaged shellfish, if they are to be frozen, at an ambient air temperature of 0°F (-18°C) or less, so that they freeze solid within twelve hours following the start of freezing.

(c) *Re-packing shucked shellfish.* When repacking shucked shellfish, a licensee dealer shall do all of the following:

1 1. Maintain repacked fresh or thawed shucked shellfish, including any portion of frozen
2 shellfish for repacking at an internal temperature of 45°F (7.2°C) or less.

3 2. Store repacked, shucked shellfish in covered containers at an ambient air temperature
4 of 45°F (7.2° C) or less.

5 (d) *Wet storage of shellstock*. A licensee dealer conducting wet storage of shellstock
6 shall do all of the following:

7 1. Follow a plan approved by the department. The plan shall include procedures for
8 ensuring water quality, washing and culling of shellstock before wet storage begins, and
9 segregation of shellstock species and lots of shellstock.

10 2. Use only shellstock harvested from areas classified by the governing authority as
11 approved or conditionally approved in the open status.

12 3. Comply with requirements in subs. (9) and (10).

13 4. Store depurated shellstock only within the facility in which the shellstock was
14 depurated.

15 5. Store and handle shellstock before wet storage to protect against conditions which
16 adversely affect shellstock survival.

17 6. Maintain shellstock in a sanitary condition.

18 7. Harvest, process, package and label shellstock from wet storage in compliance with
19 requirements of this chapter.

20 8. Keep complete and accurate records to enable a lot of shellstock to be traced back to
21 the original harvest location and wet storage location, and include the dates the shellstock was
22 held in wet storage. The records shall be maintained for at least one year.

1 9. Not commingle lots of shellstock unless in accordance with a commingling plan
2 approved by the department. If 2 or more lots of shellstock are in wet storage at the same time,
3 the identity of each lot of shellstock shall be maintained.

4 **(14) LABELING SHUCKED SHELLFISH.** (a) The licensee dealer shall maintain lot integrity
5 when shucked shellfish are stored using in-plant reusable containers.

6 (b) If the licensee dealer uses returnable containers to transport shucked shellfish to other
7 licensee dealers in Wisconsin or certified dealers in other states for the purpose of further
8 processing or packing, the returnable containers are exempt from the labeling requirements in
9 this subsection. When returnable containers are used, the shipment shall be accompanied by a
10 transaction record containing the original shucker-packer's name and license or certification
11 number, the shucking date, and the quantity of shellfish per container and the total number of
12 containers.

13 (c) If the licensee dealer uses master shipping cartons, the master cartons are exempt
14 from the labeling requirements in this subsection when the individual containers within the
15 carton are properly labeled.

16 (d) The licensee dealer shall label each individual package containing fresh or frozen
17 shucked shellfish meat in a legible and indelible form and in accordance with applicable
18 requirements for declaration of quantity and drained weight specified in 21 CFR Parts 161.30
19 and 161.130.

20 (e) Each package containing less than 64 fluid ounces of fresh or frozen shellfish shall
21 have the certification number on the label, and a "sell by date" which provides a reasonable
22 subsequent shelf-life or the words "best if used by" followed by a date when the product would
23 be expected to reach the end of its shelf-life. The date shall consist of the abbreviation for the

month and number of the day of the month. For frozen shellfish, the year shall be added to the date.

(f) Each package containing more than 64 fluid ounces of fresh or frozen shellfish shall have the certification number on the label, and the "date shucked."

1. The date shucked for fresh shellfish shall consist of the number of the day of the year or the month and the number of the day of the month.

2. The date shucked for frozen shellfish shall include the number of the day of the year or the month and the number of the day of the month, and the year.

3. The date shucked shall appear on the lid and sidewall, or bottom of disposable containers.

(g) If the licensee dealer thaws and repacks frozen shellfish, the licensee dealer shall label the shellfish container as previously frozen.

(h) If the licensee dealer freezes fresh shucked shellfish, the licensee dealer shall label all frozen shellfish as frozen in type of equal prominence immediately adjacent to the type of shellfish and the year shall be included in the date on the label.

(i) The licensee dealer shall include on each package of fresh or frozen shucked shellfish a consumer advisory with the statement "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(j) The licensee dealer shall provide all label information in a legible and indelible form and in accordance with applicable requirements for declaration of quantity and drained weight specified in 21 CFR Parts 161.30 and 161.130.

1 (k) If the licensee dealer elects to repack molluscan shellfish, the licensee dealer shall
2 pack and label all shellfish in accordance with this subsection, except that the original date of
3 shucking shall be used in establishing the sell by date.

4 (15) LABELING OF IN-SHELL PRODUCT (a) Licensee dealers, packing any container
5 holding in-shell product, shall label the container with tags that are legible and indelible and
6 indicate all of the following:

7 1. The licensee dealer's name, address, and certification number assigned by the
8 department.

9 2. The original shellstock shipper's certification number. If the shellfish has been
10 depurated, the original shellstock shipper's certification number is not required.

11 3. The depuration cycle number or lot number, if the shellfish has been depurated.

12 4. The most precise identification of the harvest location as is practicable, including the
13 capital initials of the state of harvest, and that state authority's designation of the growing area
14 by indexing, administrative or geographic designation.

15 5. When in-shell product has been transported across state lines and placed in wet
16 storage in a licensee dealer's operation, the statement "This product is a product of (name of
17 state) and was wet stored at (facility certification number) from (date) to (date) ."

18 6. A "sell by date" which provides a reasonable subsequent shelf-life or the words "best
19 if used by" followed by a date when the product would be expected to reach the end of its shelf-
20 life. The date shall consist of the abbreviation for the month and number of the day of the
21 month. For frozen shellfish, the year shall be added to the date.

22 7. The type and quantity of in-shell product.

1 8. In bold capitalized type on each tag, the statement **"THIS TAG IS REQUIRED TO**
2 **BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND**
3 **THEREAFTER KEPT ON FILE FOR 90 DAYS."**

4 9. The statement "Keep Refrigerated" or an equivalent statement.

5 (b) The container for all in-shell products intended for raw consumption shall bear a
6 consumer advisory with the statement: "Consuming raw or undercooked meats, poultry, seafood,
7 shellfish or eggs may increase your risk of foodborne illness, especially if you have certain
8 medical conditions."

9 (c) If the in-shell product is removed from the original container, the tag on the new
10 container shall meet the requirements of par. (a).

11 (d) When in-shell product intended for retail sale is packed in containers of 5 pounds or
12 less, and shipped in a master container which includes a tag complying with par. (a), then
13 labeling of the individual containers is not required to comply with par. (a), but may be labeled
14 in some other manner with indelible, legible information which is adequate to trace the in-shell
15 shellfish back to the lot which it was derived. The consumer advisory required in part (b) shall
16 be included on each individual retail package.

17 **(16) SHELLFISH STORAGE AND HANDLING.** . When storing and handling shellfish, the licensee
18 dealer shall do all of the following:

19 (a) Assure that shellstock is reasonably free of sediment and culled.

20 (b) Assure that shucking buckets are completely empty at the packing room so that no
21 overage is returned to the shucker.

22 (c) Inspect incoming shipments, and reject dead or inadequately protected shellstock.

1 (d) Assure that no usable containers or container covers bearing a certification number
2 different from the one issued for those premises are present unless documentation exists to verify
3 the legitimate source of the containers or container covers, and the containers contain shellfish
4 from that source.

5 (e) Maintain shellfish received frozen in the frozen condition during storage.

6 (f) Assure that no shellstock is commingled during shucking unless all shellfish is from
7 licensee dealers in Wisconsin or certified dealers outside Wisconsin included in a commingling
8 plan approved by the department.

9 (17) TRANSPORTATION. (a) *Transportation of shellstock* Trucks or other vehicles used to
10 transport shellstock shall meet all of the following requirements:

11 1. All trucks used to transport shellstock shall be properly constructed, operated, and
12 maintained by the harvester, or person who transports shellstock from the harvester to the
13 original licensee dealer to prevent contamination, deterioration, and decomposition of shellstock.

14 2. Storage bins on trucks or other vehicles used in the transport of shellstock for direct
15 marketing shall be kept clean with potable water; and provided with effective drainage.

16 3. Shellstock shall be transported in refrigerated trucks when the shellstock has been
17 previously refrigerated or when ambient air temperature and time of travel are such that
18 unacceptable bacterial growth or deterioration may occur.

19 4. A pre-chilling truck or other refrigerated vehicle is required when ambient air
20 temperatures are such that unacceptable bacterial growth or deterioration may occur.

21 5. When any mechanical refrigeration unit is used, the unit shall be equipped with
22 automatic controls, and capable of maintaining the ambient air temperature in the storage area at
23 a temperature of 45°F (7.2°C) or less.

1 6. No animals shall be allowed in any part of any truck or other vehicle where shellstock
2 is stored.

3 7. Transportation agents or common carriers used by a shipper are not required to be
4 certified.

5 (b) *Transportation storage containers.* Transportation storage containers shall meet all of
6 the following requirements:

7 1. Containers used to transport shellstock shall be clean, constructed of food-contact
8 grade material and free of any substance or organisms that may cause the shellstock to become
9 adulterated.

10 2. Any container to be used more than one time to store and transport shellstock shall be
11 constructed to allow easy cleaning, maintained to prevent product contamination, and cleaned
12 with potable water and a detergent, other cleaning chemical or sanitizer acceptable for food
13 contact surfaces and used according to the manufacturer's specifications.

14 (c) *Shipment protection from cross contamination.* Molluscan shellfish shipments shall
15 be protected from cross contamination and meet all of the following requirements:

16 1. Except for bulk shipments, when the entire shipment consists of molluscan shellfish
17 products, shellstock shall be shipped on pallets. If the conveyance does not have a channeled
18 floor, pallets shall be used for all shellfish.

19 2. When the conveyance has mixed shipments, the molluscan shellfish shall be shipped
20 only when molluscan shellfish products are protected from contamination by the other cargo, all
21 cargo is placed on pallets, and no other cargo is placed on or above the molluscan shellfish
22 unless all cargo is packed in sealed, crush resistant, leak-proof and waterproof containers.

(d) *Shipping times.* When shipping molluscan shellfish or shellstock, the shipper must ensure all of the following conditions are met:

1. When the expected shipping time for any molluscan shellfish or shellstock is 4 hours or less, the shipper shall use ice or mechanical refrigeration to maintain the required temperature of the molluscan shellfish or shellstock. Mechanical refrigeration units shall be equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of 45°F (7.2°C) or less. The shipper is not required to provide thermal recorders during shipment. Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.

2. When the expected shipping time is greater than 4 hours, the shipper shall ship all shellfish in mechanically refrigerated conveyances which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at a temperature of 45° F (7.2°C) or less, or in containers, the internal ambient air temperature of 45°F (7.2°C) or less.

a. Unless the shipper has a HACCP plan approved by the department with an alternate means of monitoring time-temperature, the shipper shall ensure that a suitable time-temperature recording device accompanies each shipment of shellfish.

b. The shipper shall note the date and time shown on the temperature-indicating device.

c. Each shipment receiver shall record the date and time shown on the temperature-indicating device when the shipment is received, and the doors of the conveyance or the containers are opened.

d. The final shipment receiver shall keep the time-temperature recording chart or other record of time- temperature in a file and shall make it available to the department upon request.

e. An inoperative temperature-indicating device shall be considered a failure to provide the required recording device.

(18) HACCP PLAN. (a) Prior to licensing and certification as a licensee dealer, each applicant shall develop any necessary HACCP plans to comply with subch. II and 21 CFR Part 123, addressing food safety hazards in its operations. HACCP plans shall be approved by the department as part of the license application process. The HACCP plan for shellfish processing shall include all of the following:

1. For a shellstock shipper, the critical control point of shellstock shipping.

2. For a shucker-packer, repacker, or reshipper, the critical control points of receiving, shellstock or in-shell product storage, processing, and shucked meat storage, and shipping, as appropriate.

3. A HACCP plan which includes the receiving critical control point shall include critical limits for the receiving critical control point that ensure all of the following:

a. Shellstock is obtained from a licensed harvester who has harvested the shellstock from an approved area or a conditionally approved area in the open status as indicated by the tag, and identified the shellstock with a tag on each container or transaction record on each bulk shipment.

b. Shellstock, if obtained from a dealer other than the original harvester, is shipped adequately iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature, or with an internal temperature of 50°F (10°C) or less, or in a conveyance capable of lowering the temperature of the shellstock and maintaining it at 50°F (10°C) or less, and is identified with a tag on each container or transaction record with each bulk shipment.

c. In-shell product is obtained from a dealer who has shipped the in-shell product adequately iced, or in a conveyance with an ambient air temperature at or below 45° F (7.2°C), or with an internal temperature of 45° F (7.2°C) or less, and the in-shell product is identified with a tag on each container.

4. A HACCP plan which includes the shellstock or in-shell product storage critical control point shall include critical limits for the shellstock or in-shell product storage critical control point that ensure any of the following:

a. Shellstock, once placed under temperature control and until sale to the processor or final consumer, shall be iced or placed and stored in a storage area or conveyance with ambient air temperature maintained at 45° F (7.2°C) or less, and not permitted to remain without ice, mechanical refrigeration or other methods of refrigeration approved by the department for more than 2 hours at points-of-transfer such as loading docks.

b. In-shell products shall be iced or placed and stored in a storage area or conveyance with ambient air temperature maintained at 45°F (7.2°C) or less.

5. A HACCP plan which includes the processing critical control point shall include critical limits for the processing critical control point that ensure any of the following.

a. Shucked molluscan shellfish from shellstock that has not been refrigerated before shucking shall be chilled to an internal temperature of 45°F (7.2°C) or less, within 3 hours of shucking.

b. Shucked molluscan shellfish from shellstock that has been refrigerated before shucking shall be chilled to an internal temperature of 45°F (7.2°C) or less, within 4 hours of removal from refrigeration.

c. Shucked molluscan shellfish from heat shocked shellstock shall be chilled to an internal temperature of 45°F (7.2°C) or less, within 2 hours after the heat shock process.

d. Heat shocked shellstock that are cooled and held under refrigeration for later shucking shall be chilled to an internal temperature of 45°F (7.2°C) or less, within 2 hours after the heat shock process.

e. In-shell product is processed such that the internal temperature of the shellfish meat shall not exceed 45°F (7.2°C) for more than 2 hours during processing.

f. Shucked shellfish that are received and repacked shall not exceed an internal temperature of 45°F (7.2°C) for more than 2 hours.

6. A HACCP plan which includes the shucked meat storage critical control point shall include critical limits for the shucked meat storage critical control point that ensure shucked and packed shellfish are stored in covered containers at an ambient air temperature of 45°F (7.2°C) or less, or covered with ice.

7. A HACCP plan which includes the shellstock shipping critical control point shall include critical limits for the shellstock shipping critical control point that ensure the shellstock containers are labeled and tagged in compliance with the requirements in sub. (10).

8. If a licensee dealer will be using heat shock, the licensee dealer shall include heat shock as a critical control point in the HACCP plan and ensure that heat shock does not change the physical and organoleptic properties of the species, kill the shellfish prior to shucking, or increase microbial deterioration of the shucked shellfish.

(19) SHIPPING DOCUMENTS AND TRANSACTION RECORDS. (a) *Shipping documents*. Each licensee dealer shall maintain shipping documents that meet the following requirements:

1 1. Each shellfish shipment shall be accompanied by a shipping document which contains
2 the name, address, and certification number of the shipping licensee dealer, the name and address
3 of the receiving facility, and the kind and quantity of the shellfish product.

4 3. The licensee dealer shall maintain in a file, a copy of the completed shipping
5 document and make the shipping document available to the department upon request.

6 4. If the shipment is subdivided to different facilities, each receiving facility shall
7 maintain records sufficient to trace the portion received back to the original shipment.

8 5. Shellstock that is shipped bearing a restricted use tag shall only be shipped to a
9 licensed shucker-packer and shall include specific language detailing the intended use of the
10 shellstock.

11 (b) *Transaction records.* Each licensee dealer shall maintain transaction records that
12 meet the following requirements:

13 1. Each licensee dealer shall have a business address at which transaction records are
14 maintained.

15 2. Each licensee dealer shall maintain complete, accurate, and legible records of the
16 required information.

17 3. Transaction records shall be sufficient to do all of the following:

18 a. Document that the shellfish are from an authorized source.

19 b. Permit a container of shucked shellfish to be traced back to the specific incoming lot of
20 shucked shellfish or shellstock from which it was taken.

21 c. Permit a lot, or commingled lots, of shucked shellfish or a lot of shellstock to be traced
22 back to the growing area, date of harvest, date and location of wet storage, if applicable, and if
23 possible, the harvester or group of harvesters.

1 4. Purchases and sales shall be recorded in a permanently bound ledger book or using
2 other recording methods acceptable to and approved by the department.

3 5. The transaction records shall be retained for at least one year in the case of fresh
4 shellfish, and for at least 2 years or the shelf-life of frozen shellfish, whichever is longer.

5 6. If computer records are maintained, the records shall be made available for inspection
6 by the department.

7 **(20) ILLNESS OUTBREAKS ASSOCIATED WITH SHELLFISH.**

8 (a) At any time shellfish are potentially implicated in an illness outbreak involving at
9 least 2 persons not from the same household (or at least one person in the case of paralytic
10 shellfish poisoning), the department shall determine whether an epidemiological association
11 exists between the illness and the shellfish consumption by reviewing each consumer's food
12 intake history and the shellfish handling practices of the consumer and retailer.

13 (b) When the department has determined an epidemiological association exists between
14 an illness outbreak and shellfish consumption, the department shall conduct an investigation of
15 the outbreak within 24 hours to determine whether the illness is related to the shellfish growing
16 area or to post-harvest contamination or mishandling.

17 (c) Upon completion of the investigation, the department shall notify receiving states and
18 the United States food and drug administration of the findings, and take appropriate steps in
19 cooperation with the licensee dealer to recall the affected product and, if necessary, inform
20 consumers about the outbreak and associated product.

21 **SECTION 5. EFFECTIVE DATE AND INITIAL APPLICABILITY.** This rule take effect on the
22 first day of the month following publication in the Wisconsin administrative register, as provided
23 in s. 227.22 (2) (intro), Stats.

Dated this _____ day of _____, _____.

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By: _____
Ben Brancel
Secretary

Wisconsin Department of Agriculture, Trade and Consumer Protection

Business Impact Analysis¹

Rule Subject: Wisconsin's Food Processing Plants and
Shellfish Shippers and Processors
Adm. Code Reference: ATCP 70
Rules Clearinghouse #: 12-037
DATCP Docket #: 11-R-5

Rule Summary

This rule modifies current Wisconsin food processing plant rules administered by the Department of Agriculture, Trade and Consumer Protection (DATCP). Among other things, this rule:

- Defines terms related to activities associated with the receipt, processing, repacking, labeling, storage, and shipping of molluscan shellfish.
- Modifies current rules to include provisions of the National Shellfish Sanitation Program (NSSP) and the guidelines of the ISSC related to receiving, processing, repacking, labeling, storage, and shipping molluscan shellfish for wholesale interstate and intrastate trade.
- Applies existing standards for facilities, sanitation, and personal hygiene in food processing plants to molluscan shellfish shippers, reshippers and reproducers.
- Sets standards for critical control points, critical limits, record-keeping and traceability, consistent with NSSP guidelines.

Business Impact

This rule will have a positive impact on businesses in Wisconsin. Currently, Wisconsin businesses may receive and process molluscan shellfish from out of state, but may only sell these products within Wisconsin. . Wisconsin does not produce molluscan shellfish, but some businesses bring shellfish in from other states and package and reprocess it for sale within the state. This rule will allow Wisconsin businesses to expand their markets for shellfish by allowing them to process and sell molluscan shellfish in interstate commerce.

¹ This analysis includes, but is not limited to, a small business analysis ("regulatory flexibility analysis") under ss. 227.114 and 227.19(3)(e), Stats.

This rule will provide businesses with the option, under a food processing plant license, of processing and repackaging shipments of molluscan shellfish in Wisconsin to meet the needs of their customers in other states. These changes will put Wisconsin on an equal footing with molluscan shellfish shippers and processors in Illinois – specifically in the Chicago area. This rule will also provide an incentive to large wholesalers that operate in Minnesota, Iowa and the Dakotas to locate molluscan shellfish processing operations in Wisconsin.

Effect on Small Business

This rule will have a positive impact on businesses in Wisconsin. Currently, Wisconsin businesses may receive and process molluscan shellfish from out of state, but may only sell these products within Wisconsin. This rule will allow Wisconsin businesses to expand their markets for shellfish by allowing them to process and sell molluscan shellfish in interstate commerce.

The implementation costs for businesses to participate in this program are expected to be minimal. The provisions of this rule are consistent with general facility and sanitation standards that food processors must already meet. Businesses that choose to participate in the program would not need to extensively modify existing facilities or implement unusually burdensome recordkeeping. Participation in the program is voluntary and only businesses that choose to sell molluscan shellfish in interstate commerce would be required to meet the requirements. There will be no additional licensing fees beyond those already required for a food processing plant license.

This rule will primarily benefit large businesses that provide wholesale food products to retail food establishment, restaurants, and other wholesale food industries nationwide. Small businesses are unlikely to participate in this program, with current regulations allowing them to receive and sell molluscan shellfish in their local market areas. Any business, regardless of size, that sells molluscan shellfish products in interstate commerce must meet NSSP requirements. A small business that chooses to participate in the program is expected to be able to easily meet program requirements. In addition, DATCP would also provide support and guidance to any small business interested in participation to ensure they meet Hazard Analysis Critical Control Points (HACCP) and other regulatory requirements.

Conclusion

The rule will allow certain Wisconsin businesses to increase sales of molluscan shellfish in interstate commerce, while also helping to protect the public health of consumers who purchase molluscan shellfish. Implementation costs associated with this rule are expected to be minimal.

Dated this 5th day of December, 2012.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By Steven C. Ingham
Steven C. Ingham, Administrator,
Division of Food Safety

**ADMINISTRATIVE RULES
FISCAL ESTIMATE AND
ECONOMIC IMPACT ANALYSIS**

Type of Estimate and Analysis

☐ Original ☒ Updated ☐ Corrected

Administrative Rule Chapter, Title and Number

ATCP 70, Food Processing Plants

Subject

Wisconsin's Shellfish Shippers and Processors

Fund Sources Affected

☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG SEG-S

Chapter 20, Stats. Appropriations Affected

Fiscal Effect of Implementing the Rule

☒ No Fiscal Effect
☐ Indeterminate

☐ Increase Existing Revenues
☐ Decrease Existing Revenues

☐ Increase Costs
☒ Could Absorb Within Agency's Budget
☐ Decrease Costs

The Rule Will Impact the Following (Check All That Apply)

☒ State's Economy
☐ Local Government Units

☒ Specific Businesses/Sectors
☐ Public Utility Rate Payers

Would Implementation and Compliance Costs Be Greater Than \$20 million?

☐ Yes ☒ No

Policy Problem Addressed by the Rule

This proposed rule would modify ch. ATCP 70, Food Processing Plants, to incorporate changes that apply to processing molluscan shellfish (e.g., oysters, clams, mussels and certain forms of scallops). Under current rules, food processing plants in Wisconsin that perform fish processing may receive molluscan shellfish from another state and process the shellfish for final sale only within Wisconsin. The proposed rule would establish a program that allows Wisconsin food processing plants, that choose to participate in the program, to process and repack molluscan shellfish for sale in other states and internationally. In general, the proposed rule adopts portions of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (2009), which sets the sanitary control standards for molluscan shellfish for human consumption.

The proposed rule would allow Wisconsin to become a member of the Interstate Shellfish Sanitation Conference (ISSC). ISSC is the primary voluntary national organization of state shellfish regulatory officials. ISSC provides guidance and counsel on matters for the sanitary control of shellfish. ISSC entered into a Memorandum of Understanding with the United States Food and Drug Administration (FDA) to create a federal and state cooperative program called the National Shellfish Sanitation Program (NSSP). NSSP promotes uniformity and improves the sanitation of shellfish movement in interstate commerce. Participating states codify this guidance to regulate the processing of molluscan shellfish in their jurisdictions for interstate commerce and FDA recognizes regulations based on the guidance as suitable for ensuring compliance with the Federal Food, Drug and Cosmetic Act. Under the rule, Wisconsin food processing businesses that meet the standard would then be certified to process and ship shellfish in interstate commerce. Thirty-eight other states currently participate in ISSC. The rule does all of the following:

- Defines terms related to activities associated with the receipt, processing, labeling, storage, and shipping of molluscan shellfish.
- Modifies current rules to include provisions of NSSP and the guidelines of ISSC related to receiving, processing, repacking, labeling, storage, and shipping molluscan shellfish for wholesale interstate and

intrastate trade.

- Applies existing standards for facilities, sanitation, and personal hygiene in food processing plants to molluscan shellfish shippers and reproducers.
- Sets standards for critical control points, critical limits, record-keeping, and traceability consistent with NSSP guidelines.

Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

Businesses and Business Sectors

The rule was requested by businesses that expressed an interest in processing and repackaging molluscan shellfish for sale in other states. This rule will primarily benefit large businesses that provide wholesale food products to retail food establishments, restaurants, and other wholesale food industries nationwide. The rule will provide businesses with the option, under a food processing plant license, of processing and repackaging shipments of molluscan shellfish in Wisconsin to meet the needs of their customers in other states.

Small businesses are unlikely to participate in this program, with current regulations allowing them to receive and sell molluscan shellfish in their local market areas. A small business licensed as a food processor and who chooses to participate in the program is expected to be able to easily meet program requirements.

The provisions of this rule are consistent with general facility and sanitation standards that food processors must already meet. Businesses that choose to participate in the program would not need to extensively modify existing facilities or implement unusually burdensome recordkeeping. Participation in the program is voluntary and only businesses that choose to sell molluscan shellfish in interstate commerce would be required to meet the requirements. There will be no additional licensing fees beyond those already required for a food processing license.

State's Economy

Wisconsin does not produce molluscan shellfish, but some businesses bring shellfish in from other states and package and reprocess it for sale within the state. This rule will allow Wisconsin businesses to expand their markets for shellfish by allowing them to process and sell molluscan shellfish in interstate commerce. The proposed rule would establish a program that allows Wisconsin food processing plants, that choose to participate in the program, to process and repack molluscan shellfish for sale in other states and internationally. Thirty-eight other states participate in ISSC. For example, the rule will put Wisconsin on an equal footing with molluscan shellfish shippers and processors in Illinois, specifically in the Chicago area. The rule will also provide an incentive to large wholesalers that operate in Iowa, Minnesota and the Dakotas to locate molluscan shellfish processing operations in Wisconsin.

Local Governmental Units and Public Utility Rate Payers

The rule will have no impact on local governmental units or public utility rate payers.

Economic Impact Analysis Comments

DATCP posted the proposed hearing draft rule online as required under s. 227.137, Stats., and contacted appropriate organizations to solicit information and advice from businesses, business sectors, associations, local governmental units and individuals that may be affected by the proposed rule. The department did not receive any comments on the economic impact of the rule.

Fiscal Impact

This rule will not have a significant fiscal impact on state government and DATCP will absorb any costs with current budget and staff since food processing plants are already regulated by DATCP. This rule will have no fiscal effect on local governments.

Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

This rule will have a positive impact on business in Wisconsin. Currently, Wisconsin businesses may receive and process molluscan shellfish from out of state, but may only sell these products within Wisconsin. This rule will also Wisconsin businesses to expand their markets for shellfish by allowing them to process and sell molluscan shellfish in interstate commerce. If the rule is not adopted, Wisconsin will continue to have an economic disadvantage relative to other states, such as Illinois and Michigan, that have adopted the standards and allow interstate sales of processed and repackaged molluscan shellfish.

Long Range Implications of Implementing the Rule

There are no long range negative implications of implementing the rule. The rule will allow certain Wisconsin businesses to increase sales of molluscan shellfish in interstate commerce, while also helping to protect the public health of consumers who purchase molluscan shellfish.

Compare With Approaches Being Used by Federal Government

There are no federal laws related to the transportation and processing of molluscan shellfish. However, FDA administers the National Shellfish Sanitation Program (NSSP), which developed a model ordinance that states may use to develop uniform shellfish regulations. Compliance with the model ordinance is deemed consistent with meeting applicable provisions in the Federal Food, Drug and Cosmetic Act.

Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois and Michigan currently participate in NSSP. Unlike this proposed rule, Illinois and Michigan require molluscan shellfish processors to pay additional fees to participate in the program. Iowa and Minnesota do not participate. These states may be potential customers for molluscan shellfish sold by Wisconsin businesses.

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